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PHA 42630.1 (01381/1/US)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Diane T. Stephenson et al
Serial No. 10/829,009
Filed April 21, 2004
Confirmation No. 6778

Art Unit 1614

For COMPOSITIONS OF A CYCLOOXYGENASE-2 SELECTIVE INHIBITOR
AND A SODIUM ION CHANNEL BLOCKER FOR THE TREATMENT OF
CENTRAL NERVOUS SYSTEM DAMAGE

July 30, 2004

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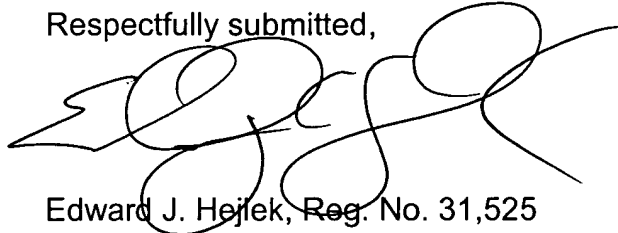
INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R.1.56, applicants submit the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicants submit herewith copies of the foreign patent documents and literature references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the

date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

Respectfully submitted,

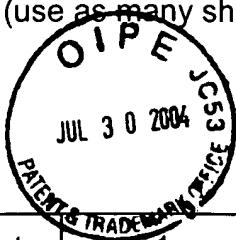
A handwritten signature in black ink, appearing to read 'E. Hejlek', with a stylized flourish extending to the right.

Edward J. Hejlek, Reg. No. 31,525
SENNIGER, POWERS, LEAVITT & ROEDEL
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EJH/cms
*Enclosures

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PTO/SB/08A				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/829,009
				Filing Date	April 21, 2004
				Confirmation Number	6778
				First Named Inventor	Diane T. Stephenson
				Group Art Unit	1614
				Examiner Name	
Sheet	1	of	4	Attorney Docket No.	PHA 42630:1 (01381/1/US)



U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
		Number	Kind Code ² (if known)				
	1	5,392,598		White et al	02/28/1995		
	2	5,466,823		Talley et al	11/14/1995		
	3	5,521,207		Graneto	05/28/1996		
	4	5,633,272		Talley et al	05/27/1997		
	5	5,932,598		Talley et al	08/03/1999		
	6	6,034,256		Carter et al	03/07/2000		
	7	6,077,850		Carter et al	06/20/2000		
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office	Number ⁴	Kind Code ² (if known)			
	8	WO	91/08760		Brigham and Women's Hospital	06/27/1991	
	9	WO	92/16192		Amgen Inc.	10/01/1992	
	10	WO	98/03484		Merck Frosst Canada Inc.	01/29/1998	

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	11	WO	00/24719		Abbott Laboratories	05/04/2000	
OTHER ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁶
	12	ALBERS, "Rationale for Early Intervention in Acute Stroke", American Journal of Cardiology, 1997, 804(4C): 4d-10d					
	13	GIERSE et al, "Expression and Selective Inhibition of the Constitutive and Inducible Forms of Human Cyclo-oxygenase", Biochemical Journal, 1995, 305: 479-484					
	14	GRAHAM et al, "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion", Journal of Pharmacol and Experimental Therapeutics, 1994, 269(2): 854-859					
	15	GURBEL et al, "Effects of Reteplase and Alteplase on Platelet Aggregation and Major Receptor Expression During the First 24 Hours of Acute Myocardial Infarction Treatment", Journal of the American College of Cardiology 31: 1466-1473, 1998					
	16	GURBEL et al, "Increased Baseline Levels of Platelet P-Selectin, and Platelet-Endothelial Cell Adhesion Molecule-1 in Patients with Acute Myocardial Infarction as Predictors of Unsuccessful Thrombolysis", Coronary Artery Disease, 1998, 9(7): 451-456					
	17	HEWITT et al, "The Use-Dependent Sodium Channel Blocker Mexiletine is Neuroprotective Against Global Ischemic Injury", Brain Research, 2001, 898(2): 281-287					
	18	IADECOLA et al, "Reduced Susceptibility to Ischemic Brain Injury and N-Methyl-D-Aspartate-Mediated Neurotoxicity in Cyclooxygenase-2-Deficient Mice", PNAS, 2001, 98: 1294-1299					
	19	KRAZTER et al, "Simulation of Primary Haemostasis in Vitro", Haemostasis, 1985, 15: 357-362					
	20	LAPCHAK et al, "Neuroprotection by the Selective Cyclooxygenase-2 Inhibitor SC-236 Results in Improvements in Behavioral Deficits Induced by Reversible Spinal Cord Ischemia", 2001, Stroke, 32(5): 1220-1230					

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	21	LIPPERT et al, "Over-Addictive Protective Effect of Dizocilpine and NBQX Against Neuronal Damage", European Journal of Pharmacology, 1994, 253: 207-213	
	22	LONGA et al, "Reversible Middle Cerebral Artery Occlusion without Craniectomy in Rats", Stroke, 1989, 20: 84-91	
	23	NAGAYMA et al, "The Cyclooxygenase-2 Inhibitor NS-398 Ameliorates Ischemic Brain Injury in Wild-Type Mice but not in Mice with Deletion of the Inducible Nitric Oxide Synthase Gene", Journal of Cerebral Blood Flow Metabolism, 1999, 19(11): 1213-1219	
	24	NEWMAN, "Aerosols and the Lung: Clinical and Experimental Aspects", Chapter 9 - "Therapeutic Aerosols", Butterworths, London, England, 1984, p. 197-224	
	25	OGAWA et al, "Super-Delayed Changes of Muscarinic Acetylcholine Receptor in the Gerbil Hippocampus Following Transient Ischemia", Advances in Experimental Medicine and Biology, 287: 343-347	
	26	OGAWA et al, "Post-Ischemic Administration of Bifemelane Hydrochloride Prohibits Ischemia-Induced Depletion of the Muscarinic M ₁ -Receptor and its mRNA in the Gerbil Hippocampus", Brain Research, 591: 171-175	
	27	SCHELLER et al, "XLIII-15. Extracellular Changes of Glutamate in the Periinfarct Zone. Effect of Lubeluzole", 1995, Journal of Cerebral Blood Flow and Metabolism, 15:S379 (Sup. 1)	
	28	SEREBRUANY et al, "Heterogeneity of Platelet Aggregation and Major Surface Receptor Expression in Patients with Acute Myocardial Infarction " American Heart Journal, 136: 398-405, 1998	
	29	SEREBRUANY et al, "Effect of Thrombolytic Therapy on Platelet Expression and Plasma Concentration of PECAM-1 (CD31) in Patients With Acute Myocardial Infarction", Arterioscler Thromb Vasc Biol 19: 153-158, 1999	
	30	TANAKA et al, "Effects of Blockade of Voltage-Sensitive Ca ²⁺ /Na ⁺ Channels by a Novel Phenylpyrimidine Derivative, NS-7, or CREB Phosphorylation in Focal Cerebral Ischemia in the Rat", 2000, Brain Research, 873(1): 83-93	
	31	TANAKA et al, "Post-Ischemic Administration of the Acetylcholinesterase Inhibitor ENA-713 Prevents Delayed Neuronal Death in the Gerbil Hippocampus" Neurochemical Research, 1995, 20(6):663-667	

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	32	TURSKI et al, "ZK200775: A Phosphonate Quinoxalinedione AMPA Antagonist for Neuroprotection in Stroke and Trauma", PNAS, 1998, 95: 10960-10965	
	33	XIE et al, "Effects of the sodium channel blocker tetrodotoxin (TTX) on cellular ion homeostasis in rat brain subjected to complete ischemia," Brain Research, 1994, 652:216-222	
	34	YAMASAKI et al, "The Possible Involvement of Tetrodotoxin-Sensitive Ion Channels in Ischemic Neuronal Damage in the Rat Hippocampus", Neuroscience Letters, 1991, 121: 251-254	

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